

Atty. Dkt. No. 0709.010.0002  
United States Serial No. 10/721,091

## REMARKS/ARGUMENTS

### I. INTRODUCTORY REMARKS

#### A. THE INTERVIEW OF SEPTEMBER 1, 2005

Applicants and their representative thank the Examiner and his Supervisor for their courtesy of extending an interview on September 1, 2005. The substance of the interview is discussed herein.

#### B. RESPONSE TO RESTRICTION REQUIREMENT

In response to Applicants' submission of additional claims 40-58, the Examiner issued a restriction requirement and stated that "[s]ince applicant has received an action on the merits for the originally presented invention (*i.e.*, invention I [claims 1-18]); this invention is constructively elected..." *Prosecution History, U.S. Serial No. 10/721,091, Office Action dated July 29, 2005*, page 4. Applicants acknowledge the Examiner's restriction and withdraw the restricted claims herein. Applicants reserve the right to pursue the withdrawn claims in subsequent applications.

#### C. SUPPORT FOR THE CLAIM AMENDMENTS

Claims 1, 6 and 12 have been amended, and claims 10 and 11 have been canceled. Support for the amended claims can be found throughout the specification and the originally presented claims. Specifically, support for the amendments to claims 1 and 6 can be found at least in paragraphs 0017, 0018, 0026, 0029, 0033 and 0073. Claim 12 was amended to change dependency. Accordingly, the amendments to the claims do not introduce new matter to the present application.

Based on the substance of the Examiner's interview of September 1, 2005, it is Applicants' understanding that the amendments to claims 1 and 6, particularly claim 1, would not require a new search, because the amendments simply incorporate limitations from dependent claims that had previously been searched. Accordingly, entry of the claim amendments is

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earnestly solicited. Upon entry of the amendments, claims 1-9 and 12-18 would be under consideration.

## II. THE OFFICE ACTION OF FEBRUARY 8, 2005

### A. THE REJECTIONS OF CLAIMS 1-18 UNDER 35 U.S.C. §112, 2<sup>ND</sup> ¶ ARE MOOT OR TRAVERSED

#### 1. "Standard for Ascertaining Dissociation Constants"

In the Office Action dated July 29, 2005 ("the Office Action"), the Examiner alleged that claim 1 was indefinite under 35 U.S.C. §112, second paragraph because "the exact experimental conditions for measurement of the dissociation constant is not clear." *Office Action*, page 5.

In the Examiner's interview of September 1, 2005 ("the interview") Applicants pointed to Example 4 (paragraphs 0073-0075) in the specification as exemplary disclosure that would teach one of skill in the art representative experimental conditions necessary to determine dissociation constants. Applicants assert that the claims, when read in light of at least paragraphs 0073 -0075 reasonably apprise one of skill in the art as to how to ascertain the scope of the invention. Reconsideration and withdrawal of this rejection are earnestly solicited.

#### 2. Grammar of Claim 1

In the Office Action, the Examiner alleged that claim 1 was indefinite under 35 U.S.C. §112, second paragraph because the recitation of "in the measured luminescence value" appeared to be grammatically incorrect. *Office Action*, page 5. Applicants wish to thank the Examiner for bringing this perceived grammar error to their attention. Applicants have amended claim 1 accordingly. Withdrawal of this rejection is solicited.

#### 3. "And"

In the Office Action, the Examiner alleged that claim 6 was indefinite under 35 U.S.C. §112, second paragraph, "because it is not clear what values are required for calculating a ratio."

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*Office Action*, page 5. Without agreeing with the Examiner's assertions, Applicants have amended claim 6 to better capture envisioned commercial embodiments. The amendments to claim 6 render the Examiner's rejection of this claim moot. Reconsideration and withdrawal of this rejection are earnestly solicited.

#### 4. "Alexa"

In the Office Action, the Examiner alleged that claim 18 was indefinite under 35 U.S.C. §112, second paragraph, because "the recitation of proprietary trademarks (c.g., "Alexa") is indefinite." *Office Action*, page 5. Applicants' representative has conducted another search of the USPTO web-accessible trademark database and found no registered trademark of "Alexa" that is associated with a small molecule dye. Enclosed herewith is an article (Panchuk-Voloshina, N. *et al.*, J. Histochem. Cytochem. 47(9): 1179-1189 (1999)) that demonstrates that one of skill in the art would understand the term "Alexa dye" has a specific meaning, and that the specific Alexa dyes, *e.g.*, Alexa 532, have a definite structure that is readily understood by one of skill in the art. Reconsideration and withdrawal of this rejection are earnestly solicited.

#### B. THE REJECTION OF CLAIMS 1-13 AND 17-18 UNDER 35 U.S.C. §102(b) IS NOW MOOT

In the Office Action, the Examiner rejected claims 1-13 and 17-18 and alleged that these claims are anticipated by Lakowicz *et al.* (U.S. Patent No. 6,197,534). Specifically, the Examiner stated that "Lakowicz *et al.* teach a method for quantifying an analyte in a sample ...." *Office Action*, page 5. Furthermore, the Examiner posited that "Lakowicz *et al.* necessarily teach a fusion protein having a dissociation constant of at least 1 mM towards said analyte, and would be so recognized by persons of ordinary skill in the art." *Office Action*, page 6. Applicants incorporate by reference their comments and arguments previously presented in their Response to Office Action of May 9, 2005. Without agreeing with the Examiner's assertion that Lakowicz *et al.* anticipates the claimed invention, Applicants have amended claim 1 to better capture envisioned commercial embodiments.

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As discussed in the interview, it is Applicants' position that Lakowicz does not teach or suggest a fusion protein having a dissociation constant of at least 1 mM, as required by the claims. Rather, Lakowicz teaches a binding protein with a *stronger* affinity than the presently claimed binding protein (See Lakowicz et al., col. 12, ll 18-21). Indeed, the limitation "dissociation constant of at least 1 mM" is intended to convey to one of skill in the art that the claimed mutant binding protein possesses a weaker affinity towards its analyte than do proteins disclosed in Lakowicz et al. Reconsideration and withdrawal of the Examiner's rejection under 35U.S.C. §102(b) is earnestly solicited.

**C. THE REJECTION OF CLAIMS 14-16 UNDER 35 U.S.C. §103(A) IS NOW MOOT**

In the Office Action dated July 29, 2005, the Examiner rejected claims 14-16 and alleged that these claims are obvious in view of Lakowicz et al. (U.S. Patent No. 6,197,534) and Tsien & Campbell (U.S. Pregrant Publication No. 2003/0059835). Specifically, the Examiner stated that "it would have been obvious to one of skill in the art to modify the method of Lakowicz et al. with the use of DsRed2(C119A) because Tsien & Campbell discovered the importance of C119 in fluorescent protein oligomerization." *Office Action*, page 7. Applicants incorporate by reference their comments and arguments previously presented in their Response to Office Action of May 9, 2005. Without agreeing with the Examiner's assertion that the combination of Lakowicz et al. and Tsien & Campbell render claims 14-16 obvious, claim 1 has been amended to better capture commercial embodiments.

As highlighted above and as discussed in the interview, it is Applicants' position that Lakowicz et al. does not teach or suggest a functional mutant binding protein with a dissociation constant of at least 1 mM, i.e., a binding protein with weakened affinity towards its analyte. Applicants assert Tsien & Campbell do not rectify these deficiencies. Also discussed in the interview, Applicants assert that the combination of Lakowicz and Tsien & Campbell does not teach each and every limitation of the presently claimed invention. Accordingly, the combination of Lakowicz and Tsien & Campbell can not render the claimed invention obvious under 35 U.S.C. §103. Reconsideration and withdrawal of this rejection are earnestly solicited.